

UnitedHealthcare® Oxford Clinical Policy

Instructions for Use

Gynecomastia Surgery

Policy Number: SURGERY 026.26 Effective Date: July 1, 2024

Table of Contents	Page
Coverage Rationale	1
Documentation Requirements	2
Definitions	2
Applicable Codes	3
Description of Services	3
Benefit Considerations	3
Clinical Evidence	3
U.S. Food and Drug Administration	6
References	6
Policy History/Revision Information	7
Instructions for Use	8

Related Policies

- Breast Reduction Surgery
- <u>Cosmetic and Reconstructive Procedures</u>
- Gender Dysphoria Treatment
- Panniculectomy and Body Contouring Procedures

Coverage Rationale

See Benefit Considerations

A mastectomy for treating Gynecomastia on a male member under age 18 is considered reconstructive and medically necessary when all the following criteria are met:

- Gynecomastia stage II, III, or IV with moderate to severe chest pain causing a <u>Functional or Physical Impairment</u> (the inability to participate in athletic events, sports, or social activities is not considered to be a Functional or Physical or physiological Impairment)
- Glandular breast tissue is the primary cause of Gynecomastia as opposed to fatty deposits (pseudogynecomastia) and is documented on physical exam and/or mammography
- Persistent Gynecomastia after cessation of prescribed medications, nutritional supplements, and appropriate screening(s) of non-prescription and/or recreational drugs or substances that have a known side effect of Gynecomastia (examples include, but are not limited to testosterone, marijuana, asthma drugs, phenothiazines, anabolic steroids, cimetidine, and calcium channel blockers)
- Gynecomastia must be present for at least two years and appropriate evaluation of medical causes with supporting laboratory testing has been normal; if so, lab tests might include, but are not limited to the following, must be performed:
 - Hormone testing (e.g., beta-human chorionic gonadotropin, estradiol, follicle-stimulating hormone, luteinizing hormone, prolactin, testosterone)
 - o Liver enzymes
 - Serum creatinine
 - Thyroid function studies

A mastectomy for treating <u>Gynecomastia</u> on a male member aged 18 and over is considered reconstructive and medically necessary when all the following criteria are met:

- Gynecomastia stage II, III, or IV with moderate to severe chest pain causing a <u>Functional or Physical Impairment</u> (the inability to participate in athletic events, sports, or social activities is not considered to be a Functional or Physical or physiological Impairment)
- Glandular breast tissue is the primary cause of Gynecomastia as opposed to fatty deposits (pseudogynecomastia) and is documented on physical exam and/or mammography
- Persistent Gynecomastia after cessation of prescribed medications, nutritional supplements, and appropriate screening(s) of non-prescription and/or recreational drugs or substances that have a known side effect of

Gynecomastia (examples include, but are not limited to testosterone, marijuana, asthma drugs, phenothiazines, anabolic steroids, cimetidine, and calcium channel blockers)

- Appropriate evaluation of medical causes with supporting laboratory testing has been normal; if so, lab tests might include, but are not limited to the following, must be performed:
 - Hormone testing (e.g., beta-human chorionic gonadotropin, follicle-stimulating hormone, estradiol, luteinizing hormone, prolactin, testosterone)
 - o Liver enzymes
 - Serum creatinine
 - o Thyroid function studies

Note: Regardless of age, if a tumor or neoplasm is suspected, a breast ultrasound and/or mammogram may be performed with further management as indicated.

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

*For code description, refer to the <u>Applicable Codes</u> section.

Definitions

The following definitions may not apply to all plans. Refer to the member specific benefit plan document for applicable definitions.

Gynecomastia: Gynecomastia is breast enlargement in boys or men due to a benign (non-cancerous) increase in breast tissue. (Endocrine Society, 2022)

American Society of Plastic Surgeons' Gynecomastia scale (ASPS, 2015):

- Grade II: Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest.
- Grade III: Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest with skin redundancy present.
- Grade IV: Marked breast enlargement with skin redundancy and feminization of the breast.

Gynecomastia Surgery UnitedHealthcare Oxford Clinical Policy **Functional or Physical Impairment**: A functional or physical, or physiological impairment causes deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired, or delayed capacity to move, coordinate actions, or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks, independent movement, performing basic life functions. (Medicare, 2023)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

Note: Coding for suction lipectomy is addressed in the Clinical Policy titled <u>Panniculectomy and Body Contouring</u> <u>Procedures</u>.

CPT Code		Description
19300	Mastectomy for gynecomastia	
		CPT [®] is a registered trademark of the American Medical Association

Description of Services

Gynecomastia is a benign proliferation of glandular breast tissue in men. Physiologic Gynecomastia is common in newborns, adolescents, and older men. Treatment is directed at minimizing emotional distress and physical discomfort. Nonphysiologic Gynecomastia may be caused by chronic conditions including but not limited to cirrhosis, hypogonadism, and renal insufficiency; use of medications, supplements, or illicit drugs; and, rarely, tumors. Discontinuing using contributing medications and treating underlying diseases is the standard of practice. Medications, such as estrogen receptor modulators and surgery, have a role in treating Gynecomastia in select patients. Mastectomy is the surgical removal of glandular breast tissue through an open incision or, more recently, through minimally endoscopic techniques. Cases considered severe may require larger incisions. (Dickson, 2012)

Benefit Considerations

Most benefit plans explicitly exclude coverage for treatment of Benign Gynecomastia. However, some states require coverage.

Refer to the member specific benefit plan document to determine availability of benefits for these procedures.

Clinical Evidence

In a systematic review, Prasetyono and colleagues (2022) examined the quality of studies and revisited the liposuctionassisted gynecomastia surgery performed through minimal incision. This systematic review was appraised using MINORS to assess the methodological quality. The results demonstrated 18 studies with 244 individuals with an average age of 23.13 years. Consistent improvement in quality of life in terms of satisfaction after surgery, along with easy handling to remove breast tissues via a small incisional design, was demonstrated with liposuction. However, the complication rates were inconsistent for liposuction throughout the studies (range = 0.06 to 26.67%). For liposuction-assisted surgery, the reoperation rate was between 0.6 and 25%. The two studies identified as 'good quality' discussed the laser-assisted liposuction technique, which showed a minor seroma complication for two individuals. Both studies demonstrated a high surgeon satisfaction rate, and one showed a high patient satisfaction rate. The authors concluded that the small incisional design for breast parenchymal removal in gynecomastia assisted by liposuction showed an excellent technical approach for consistent improvement in quality of life. Larger, good-quality methods of non-randomized case series urging better quality are necessary.

Innocenti and associates (2022) performed a systematic review of the literature related to incidences of complications for different approaches in gynecomastia correction. In total, 94 articles were obtained consisting of 7294 individuals being analyzed. Three groups were created: aspiration techniques, consisting of 874 individuals (11.98%); surgical excision techniques, consisting of 2764 individuals (37.90%); and combined techniques, consisting of 3656 individuals (50.12%). The notable complications for each group totaled 1407. In the surgical excision techniques group, there were 847

(30.64%), 130 (14.87%) in the aspiration techniques group, and 430 (11.76%) in the combined techniques group. The authors concluded that the combined use of surgical excision and aspiration techniques reduces the rate of complications compared to that of the surgical excision alone; however, the lack of unique classification and presence of several surgical methods represents a bias in the literature review.

In 2021, Trinchieri et al. conducted a systematic review and meta-analysis of randomized clinical trials concerning treatment-related gynecomastia for individuals taking spironolactone, antiandrogens, 5 alpha-reductase inhibitors, lipid-lowering, and psychotropic drugs through a systematic review and meta-analysis of randomized clinical trials. For men receiving antiandrogens, there was an increased risk of gynecomastia (OR = 17.38, 95% CI: 11.26 to 26.82; 6 trials, 9599 participants) and 5 alpha-reductase inhibitors compared to controls (OR = 1.77, 95% CI: 1.53 to 2.06; 7 series out of 6 trials, 34860 participants). Compared to controls, using spironolactone in mixed-gender populations were considered to have substantially higher odds of having gynecomastia (OR = 8.39, 95% CI: 5.03 to 13.99; 14 trials, 3745 participants). There was a noteworthy variance in the odds of having gynecomastia in an evaluation between risperidone and quetiapine (OR = 4.32, 95% CI: 1.31 to 14.27; 3 trials, 343 participants), however; no placebo-controlled trials concentrating on the risk of gynecomastia for individuals taking antipsychotic drugs was obtainable. Antiandrogens, 5 alphareductase inhibitors, and spironolactone are associated with an increased risk of developing gynecomastia.

Holzmer and colleagues, (2020) conducted a comprehensive review of the literature regarding the surgical management of gynecomastia to analyze surgical practice patterns and trends pertaining to the grade and severity of gynecomastia. The primary data points were the complication rate, including hematoma, seroma, infection, necrosis, drain use, gynecomastia grade, and surgical intervention. A total of 1112 individuals received surgical treatment for gynecomastia, with the most used technique being skin-sparing mastectomy with or without liposuction, followed by mastectomy with skin reduction. The most common complication noted was hematoma formation which comprised 5.8% of complications, followed by seroma, 2.4%. Those who routinely utilized drain placement demonstrated a higher rate of hematoma/seroma formation (9.78% vs. 8.36%; p = 0.0051). However, a limitation is a large discrepancy in the percentage of grade III individuals found in each group (50.23% vs. 4.36%; p = 0.0000). The authors concluded that there is a wide range of surgical techniques for treating gynecomastia. No definitive, universally accepted algorithm exists showing the ideal surgical approach for treating gynecomastia based on severity. An individualized approach based on gynecomastia grade and individual preference should assist the surgeon in providing the best outcomes.

A randomized controlled trial was conducted by Mohamad in 2019 to compare operative techniques; modified Benelli technique vs. subcutaneous mastectomy using periareolar incision. Participants were divided into two groups regarding their surgical technique to carry out the trial. Group A consisted of 75 individuals undergoing surgical treatment with subcutaneous mastectomy using periareolar incision, and group B included 75 individuals being managed by the modified Benelli technique. The trial results uncovered that the modified Benelli technique; had a lower operating time and retained a cosmetically acceptable position of the areola; however, there was much pleating of the skin compared to the periareolar incision. The authors concluded that the modified Benelli technique offers a reasonably simple surgical approach with an aesthetically positive outcome to treat gynecomastia with a low rate of complications and recurrences.

In a 2018 systematic review, Sollie sought to identify the psychological domains affected by gynecomastia and the effect of surgical treatment on these. Primary outcomes consisted of quality of life and several psychological domains after surgical treatment for gynecomastia, specifically, vitality, emotional discomfort, limitations due to physical aspects, and limitations due to pain. The author concluded that the impact of surgical treatment for gynecomastia is beneficial for several of the psychological domains and restrictions due to pain; however, the current level of evidence on the subject is low, requiring future studies that examine the impact of the surgical intervention for gynecomastia on psychological domains are necessary.

In 2018, Nuzzi and colleagues studied the effect of surgical treatment for gynecomastia on the quality of life in adolescents through surveys. The surveys were distributed to adolescents ages 12-21 with gynecomastia and male controls. The surveys consisted of the short-form 36v2 (SF-36), Rosenberg Self-Esteem Scale (RSES), and Eating-Attitudes Test-26. Surveys were completed at baseline, postoperatively, six months, one year, three- and five-year follow-ups. Participants in the study were 64 unaffected male controls. For the five SF-36 domains: general health, vitality, social functioning, role-emotional, and mental health, the individuals with gynecomastia scored significantly worse than controls and on the RSES. Postoperative improvements were noted in the scores of the RSES and the four SF-36 domains physical functioning, role-physical, bodily pain, and social functioning. Gynecomastia subjects scored similarly to controls in all SF-36 domains and the RSES postoperatively. Limitations in the study consist of the need for follow-up BMI data and the lack of comparison between baseline physical activity and the SF-36 survey, which confirms that the subjects have the potential for physical activity. Additional limitations include the sample size, risk for bias, and recruitment from a single, large tertiary care facility. The authors concluded that surgical treatment of gynecomastia improves the quality of

life for adolescents, especially those overweight individuals with severe gynecomastia, and measurable improvements in psychosocial and physical functioning are evident.

Zavlin et al. (2017) performed a retrospective analysis from the American College of Surgeons National Surgical Quality Improvement Program databases for adults and pediatrics to produce two cohorts that underwent surgical repair of gynecomastia. The study's goal was to assess individual's demographics, surgical outcomes, and complications. A total of 1787 individuals were identified, 204 pediatric and 1583 adult males. The mean ages were 15.8 and 39.6, respectively. The results demonstrated low surgical (3.9 and 1.9%) and medical (0.0 and 0.3%) complications within the standardized 30-day postoperative period. Children and adolescents, however, required double mean operative times compared to adults (111.3 vs. 56.7 min). The authors concluded that operative gynecomastia treatment remains a safe modality across all age groups.

Clinical Practice Guidelines

American Society of Andrology and European Academy of Andrology (ASA/EAA)

- The existence of an underlying pathology should be considered for gynecomastia in adulthood. The recommendation is to identify an apparent cause for gynecomastia in adulthood, including the use of medication recognized to be related to gynecomastia, which should not preclude a detailed investigation (moderate quality).
- Initial screening is suggested to rule out lipomastia, apparent breast cancer, or testicular cancer, which may be completed by a general practitioner or another clinical professional (very low-quality).
- In those cases where a comprehensive diagnostic workup is necessary, it should be accomplished by a specialist (very low-quality).
- The individual's medical history is recommended to incorporate information involving the onset and duration of gynecomastia, sexual development and function, and administration or abuse of substances associated with gynecomastia (moderate quality).
- The physical examination should identify signs of under-virilization or systemic disease (high quality).
- Breast examination should confirm the presence of palpable glandular tissue to differentiate from lipomastia (pseudogynecomastia) and rule out the suspicion of malignant breast tumor (high quality).
- The physical examination should involve the assessment of the genitalia to rule out the presence of a palpable testicular tumor and to identify testicular atrophy (high quality).
- Genitalia examination assisted by a testicular ultrasound, as the detection of a testicular tumor by palpation has low sensitivity (low quality).
- A set of evaluations may incorporate T, E2, SHBG, LH, FSH, TSH, prolactin, hCG, AFP, and liver adrenal function tests (low quality).
- Breast imaging may assist when the clinical examination is vague (low quality).
- If the clinical picture is suspect of a malignant lesion, a core needle biopsy should be completed (low quality).
- Watchful waiting should occur after treatment of underlying pathology or cessation of the administration/abuse of substances connected with gynecomastia (low quality).
- Treatment should be offered exclusively to men with established testosterone insufficiency (moderate quality).
- The use of selective estrogen receptor modulators (SERMs), aromatase inhibitors (Ais), or non-aromatizable androgens for treating gynecomastia, in general, is not recommended (low quality).
- Surgical treatment is only for individuals with persistent gynecomastia, which does not regress naturally or through subsequent medical therapy. The magnitude and type of surgery depend on the size of breast enlargement and the quantity of adipose tissue (low quality).

(Kanakis et al., 2019)

American Society of Plastic Surgeons (ASPS)

The 2016 ASPS's recommendations for gynecomastia surgery for adolescents:

- Unilateral or bilateral grade II or grade III gynecomastia present (per modified McKinney and Simon, Hoffman, and Kohn scales).
 - \circ $\;$ Continues more than one year following pathological sources ruled out.
 - Continues after six months of failed medical treatment for pathological gynecomastia.
- Unilateral or bilateral grade IV gynecomastia present (per modified McKinney and Simon, Hoffman, and Kohn scales).
 - Continues more than six months following pathological reasons ruled out.
 - Continues after six months of failed medical treatment for pathological gynecomastia.
- Pain and discomfort due to the distention and stiffness from the hypertrophied breast Gynecomastia may cause considerable psychological anguish, particularly in adolescents struggling with matters associated with sexual identity and self-image.

The ASPS's recommendations for gynecomastia surgery for adults:

- Breast biopsy is suggested when malignancy is presumed.
- Unilateral or bilateral grade III or IV gynecomastia present (per modified McKinney and Simon, Hoffman, and Kohn scales).
 - Continues for more than 3 to 4 months following pathological reasons ruled out.
 - Continues after 3 to 4 months of failed medical therapy for pathological gynecomastia.

Pain and discomfort due to the distention and stiffness from the hypertrophied breast.

(ASPS, 2016)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Surgeries for the treatment of gynecomastia are procedures and therefore not regulated by the FDA. Refer to the following website for additional information: <u>http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm</u>. (Accessed February 2, 2024)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [MP.012.17]

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Policy History/Revision Information

Date	Summary of Changes		
07/01/2024	Related Policies		
	Added reference link to the Clinical Policy titled Gender Dysphoria Treatment		
	Coverage Rationale		
	 Replaced references to "benign Gynecomastia" with "Gynecomastia" 		
	• Revised coverage criteria for mastectomy on a male member under age 18 :		
	 Added criterion requiring glandular breast tissue is the primary cause of Gynecomastia as opposed to fatty deposits (pseudogynecomastia) and is documented on physical exam 		
	and/or mammography		
	 Replaced criterion requiring: 		
	 "Gynecomastia or breast enlargement with moderate to severe chest pain causing a 		
	Functional or Physical Impairment" with "Gynecomastia stage II, III, or IV with moderate		
	to severe chest pain causing a Functional or Physical Impairment" "Persistent Gynecomastia after cessation of prescribed medications and appropriate 		
	 "Persistent Gynecomastia after cessation of prescribed medications and appropriate screening(s) of non-prescription and/or recreational drugs or substances that have a 		
	known side effect of Gynecomastia" with "persistent Gynecomastia after cessation of		
	prescribed medications, nutritional supplements, and appropriate screening(s) of non-		
	prescription and/or recreational drugs or substances that have a known side effect of		
	Gynecomastia" <i>"The breast enlargement</i> must be present for at least two years and appropriate		
	 "The breast enlargement must be present for at least two years and appropriate evaluation of medical causes with supporting laboratory testing has been normal" with 		
	" <i>Gynecomastia</i> must be present for at least two years and appropriate evaluation of		
	medical causes with supporting laboratory testing has been normal"		
	• Revised coverage criteria for mastectomy on a male member aged 18 and over; replaced		
	criterion requiring:		
	 "Gynecomastia or breast enlargement with moderate to severe chest pain causing a Functional or Physical Impairment" with "Gynecomastia stage II, III, or IV with moderate to 		
	severe chest pain causing a Functional or Physical Impairment"		
	o "Discontinuation of medications, nutritional supplements, and non-prescription medications		
	or substances (examples include, but are not limited to testosterone, marijuana, asthma		
	drugs, phenothiazines, anabolic steroids, cimetidine, and calcium channel blockers) that		
	have a known side effect of gynecomastia or breast enlargement and the breast size did not regress after discontinuation of use as appropriate" with "persistent Gynecomastia after		
	cessation of prescribed medications, nutritional supplements, and appropriate screening(s)		
	of non-prescription and/or recreational drugs or substances that have a known side effect of		
	Gynecomastia (examples include, but are not limited to testosterone, marijuana, asthma		
	drugs, phenothiazines, anabolic steroids, cimetidine, and calcium channel blockers)"		
	 Replaced notation language indicating "a breast ultrasound and/or mammogram may be performed, regardless of age, if a tumor or neoplasm is suspected; a breast biopsy may also be 		
	performed, regardless of age, if a tumor of neoplasm is suspected, a breast biopsy may also be performed, as indicated" with "a breast ultrasound and/or mammogram may be performed, with		
	<i>further management</i> as indicated, regardless of age, if a tumor or neoplasm is suspected"		
	Definitions		
	Updated definition of "Gynecomastia"		
	Removed definition of:		
	 Congenital Anomaly Cosmetic Procedures 		
	 Cosmetic Procedures Reconstructive Procedures 		
	Supporting Information		
	 Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information 		
	Archived previous policy version SURGERY 026.25		

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual[®] criteria, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.